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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/057,108

Applicant(s)

PLAETINCK ET AL.

Examiner

Joseph T. Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 42-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This application filed January 25, 2002, is a divisional of 09/347,311, filed July 2, 1999.

Claims 1-53 are pending.

#### ***Election/Restrictions***

Initially, it is noted that in the restriction requirement a typographical error was present for Group II, and the claims included in this group are 13-29, not 13-24.

Upon review of claims and the specification, Groups I-III are rejoined. While each group is drawn to different inventions Examiner finds that it would not be an undue burden to examine each of the inventions together, in part because of the intended use of the product in group III and the asserted utility of broad methodology in group I as it is related to group II. Applicant's election of Group I, claims 1-12 is acknowledged. No arguments is traverse of the restriction requirement, therefore the restriction between groups IV-V is maintained for reasons of record. It is noted that because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-53 are pending. Claims 42-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claim 1-41 are currently under examination as they are drawn to a micro-organism comprising an expression vector that when expressed produces double stranded

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RNA and to use of said product in a method for reducing the expression of a gene of interest in

*C. elegans*.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Specification*

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

Specifically, upon review of the specification and drawings polynucleotide sequences that are not identified by SEQ ID NOs are present (see for example throughout page 15, and Figures 1 and 2 with page 10 in brief description of the figures).

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

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***Abstract***

The abstract of the disclosure is objected to because the form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words.

Correction is required. See MPEP § 608.01(b).

***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). More specifically the fourth inventor has corrections to the spelling of his name and there is no indication when the correction was made.

***Information Disclosure Statement***

The information disclosure statement filed January 25, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-41 are rejected under 35 U.S.C. 102(a) as being anticipated by Timmons *et al.* (Nature 395:854, (October 1998)).

Claims 1-41 encompass a micro-organism comprising an expression vector that when expressed produces double stranded RNA and to use of said product in a method for reducing the expression of a gene of interest in *C. elegans*. Dependent claims set forth the use of specific promoters and genes of interest to be expressed. Timmons *et al.* report that genetic interference can be practiced in *C. elegans* and that the dsRNA can be introduced into *C. elegans* by providing the RNA in its food source. Further, the RNA can be generated by the food source through the expression of heterologous polynucleotide sequence using a promoter specific for the food source such as the T7 sequence. Timmons *et al.* teach that the bacteria expressing the dsRNA can be used to express any gene of interest and provided to *C. elegans* as a food source wherein the expression of the dsRNA results in the down regulation of the gene of interest in the *C. elegans*.

Claims 1-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Fire *et al.*(US Patent 6,506,559 B1).

Claims 1-41 are summarized above. Fire *et al.* report that genetic interference can be practiced in *C. elegans* and that the dsRNA can be introduced into *C. elegans* by providing the RNA in its food source. Further, the RNA can be generated by the food source through the expression of heterologous polynucleotide sequence using a promoter specific for the food source such as the T7 sequence. Fire *et al.* teach that the bacteria expressing the dsRNA can be used to express any gene of interest and provided to *C. elegans* as a food source wherein the expression of the dsRNA results in the down regulation of the gene of interest in the *C. elegans*.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Gomes *et al.* Eur J Pharm, 397:R3-5, 2000, provide further evidence that ingested dsRNA can target other genes in *C. elegans* by simply providing the RNA in a food source.

Crooke, US Patent 5,898,031, provides evidence of methodology known and used at the time of filing for making RNA in an organism. In particular, for the introduction of encoding sequences and for the use of RNase deficient strains for greater stability of the product.

No claim is allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

  
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